

is supported in the specification on page 8, lines 12-15. Claim 12 is supported in the specification on page 9, lines 4-6. Claims 13 and 14 are supported in the specification on page 9, lines 9-11. Claims 15 and 16 are supported in the specification on page 9, lines 11-12. Claims 17 and 18 are supported in the specification on page 9, lines 12-14. Claims 19 and 20 are supported in the specification on page 9, lines 20-22. Claims 21 and 22 are supported in the specification on page 11, lines 9-11.

Reconsideration and removal of the rejections set forth in the Action are respectfully requested.

For convenience in discussing the action, the headings in the Action are used below.

***Election/Restriction***

The provisional election of claims 1-7, drawn to a solid preparation, is affirmed without traverse. Non-elected claims 8 and 9 have been amended to recite the solid preparation in product-by-process format.

***Double Patenting***

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-4 of co-pending application No. 09/963,550. This rejection is not believed to apply to the claims of the present application as amended.

The claims of the present application as amended recite a solid preparation for dialysis comprising a mixture of (1) particles of a first composition comprising core particles comprising particles of sodium chloride, and a coating layer covering the core particles and containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate, (2) particles of a second composition comprising core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or a different sugar, and (3) an acid.

In the solid preparation for dialysis recited in the allowed claims of copending application No. 09/963,550, on the other hand, the second composition comprises particles of a sugar and a coating layer containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate.

The prior art does not provide a motive to a person of ordinary skill in the art to modify the second composition of the solid preparation for dialysis recited in the claims of copending application No. 09/963,550 by substituting a coating layer comprising the sugar of the core particles or a different sugar for the layer containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate.

Removal of the double patenting ground of rejection is respectfully requested.

***Claim Rejections - 35 U.S.C. §112***

Claims 1-7 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The rejection of claim 1 has been avoided by using numbers to identify the separate components of the preparation, i.e., (1) particles of a first composition, (2) particles of a second composition, and (3) an acid.

Regarding the rejection of claim 3, the limitations of which are now included in claim 1, the core particles comprising a sugar of the second composition are covered with a coating layer

comprising the same or a different sugar so that the average particle diameter of the second composition is made approximately the same as that of the first composition in order to obtain a solid preparation which is excellent in homogeneity. The particle diameter of a sugar is ordinarily smaller than the average particle diameter of the first composition. When the cross section of a particle of the second composition is examined by a microscope, it is believed that it is possible that the core will be distinct from the coating layer even when the same sugar is used for both the core and the coating. Moreover, it is noted that the claim does not require that the core and coating layer be visually distinct.

Removal of the 35 U.S.C. § 112 rejection is respectfully requested.

***Claim Rejections - 35 U.S.C. §102***

Claims 1-7 are rejected under 35 U.S.C. §102(b) as being anticipated by Veltman (U.S. Patent No. 4,756,838). It is respectfully submitted, however, that claim 1, both in its original form and as amended herein, does not read on the compositions disclosed in the Veltman reference. Veltman does not disclose solid preparations containing an acid. The Examiner notes in the

Action that Veltman discloses the addition of an acid to lower pH (apparently referring to Col. 17, lines 45-66). However, the acid is added to a solution and is not part of a solid preparation.

Additionally, amended claim 1 discloses a solid preparation comprising a mixture of particles of a first composition comprising core particles of sodium chloride and a coating layer of electrolytes, particles of a second composition comprising core particles of a sugar and a coating layer of a sugar, and an acid. Veltman '838 does not teach core particles and coating layers covering the core particles as required in the claims of the present application. Veltman, therefore, is insufficient to support a case of anticipation of the claims of the application under 35 U.S.C. § 102.

***Claim Rejections - 35 U.S.C. §103***

Claims 1-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Veltman. The Examiner's position is not clear and does not appear to be proper. The Examiner states that it would be obvious to modify Veltman "depending on the requirements of the patient". Such a vague suggestion is not sufficient to support a rejection under 35 U.S.C. § 103(a). The showing of the

requisite suggestion or motivation must be specific. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"). (Emphasis added). The Office has not shown the specific suggestion or motivation.

There is also no description in Veltman '838 concerning the excellent effects of the solid preparation for dialysis of the present invention, i.e., content homogeneity and no decomposition or coloration of the sugar.

Removal of the 35 U.S.C. § 130(a) rejection is also in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated June 4, 2002, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

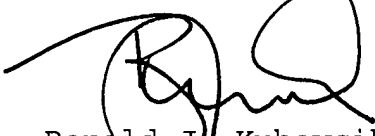
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 2, 3, and 5 have been canceled.

Claims 1, 8 and 9 have been amended as follows:

1. (Amended) A solid preparation for dialysis comprising a mixture of (1) particles of a first composition comprising core particles comprising particles of sodium chloride, and a coating layer covering the core particles and containing one or more electrolytes selected from the group consisting of [~~sodium chloride,~~] calcium chloride, magnesium chloride, potassium chloride and sodium acetate, (2) particles of a second composition [~~containing a sugar~~] comprising core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or a different sugar, and (3) an acid.

8. (Amended) A [~~process for producing a~~] solid preparation for dialysis prepared by a process comprising the following steps (1) to (3):



(1) a step of spraying an aqueous solution containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate onto core particles comprising particles of sodium chloride to obtain first coated particles, and drying the first coated particles to obtain a first composition;

(2) a step of spraying, onto core particles comprising particles of a sugar, an aqueous solution into which said sugar or a different sugar is dissolved to obtain second coated particles, and drying the second coated particles to obtain a second composition; and

(3) a step of mixing the first composition obtained in step (1) and the second composition obtained in step (2), and mixing the resultant mixture with an acid to obtain a solid preparation for dialysis.

9. (Amended) A [~~process for producing a~~] solid preparation for dialysis prepared by a process comprising the following steps

(1) to (3):

(1) a step of spraying an aqueous solution containing one or more electrolytes selected from the group consisting of calcium

chloride, magnesium chloride, potassium chloride and sodium acetate onto core particles comprising particles of sodium chloride to obtain first coated particles, and drying the particles to obtain a first composition;

(2) a step of spraying, onto core particles comprising particles of a sugar, an aqueous solution of said sugar or a different sugar to obtain second coated particles, and drying the second coated particles to obtain a second composition; and

(3) a step of mixing an acid with the first composition obtained in step (1), and subsequently mixing the resultant mixture with the second composition obtained in step (2) to obtain a solid preparation for dialysis.

The following new claims have been added to the application:

10. (New) The solid preparation for dialysis as claimed in claim 1, wherein the particles of sodium chloride have a particle diameter of about 75 to 1,700  $\mu\text{m}$  and the sodium chloride is in a crystalline state.

11. (New) The solid preparation for dialysis as claimed in claim 1, wherein the core particles of the first composition comprise up to 15% by weight of particles of an electrolyte selected from the group consisting of magnesium chloride, calcium chloride, potassium chloride, and sodium acetate.

12. (New) The solid preparation for dialysis as claimed in claim 1, wherein the coating layer of the core particles of the first composition contains up to 50% by weight of sodium chloride.

13. (New) The solid preparation for dialysis as claimed in claim 8, wherein the calcium chloride is calcium chloride dihydrate, calcium chloride monohydrate or calcium chloride anhydride.

14. (New) The solid preparation for dialysis as claimed in claim 9, wherein the calcium chloride is calcium chloride dihydrate, calcium chloride monohydrate or calcium chloride anhydride.

15. (New) The solid preparation for dialysis as claimed in claim 8, wherein the magnesium chloride is magnesium chloride hexahydrate.

16. (New) The solid preparation for dialysis as claimed in claim 9, wherein the magnesium chloride is magnesium chloride hexahydrate.

17. (New) The solid preparation for dialysis as claimed in claim 8, wherein the sodium acetate is sodium acetate anhydride or sodium acetate trihydrate.

18. (New) The solid preparation for dialysis as claimed in claim 9, wherein the sodium acetate is sodium acetate anhydride or sodium acetate trihydrate.

19. (New) The solid preparation for dialysis as claimed in claim 8, wherein the concentration of said one or more electrolytes in the aqueous solution used in step (1) is 15 to 50% by weight.

20. (New) The solid preparation for dialysis as claimed in claim 9, wherein the concentration of said one or more electrolytes in the aqueous solution used in step (1) is 15 to 50% by weight.

21. (New) The solid preparation for dialysis as claimed in claim 8, wherein the concentration of said sugar in the aqueous solution used in step (2) is 1 to 60% by weight.

22. (New) The solid preparation for dialysis as claimed in claim 9, wherein the concentration of said sugar in the aqueous solution used in step (2) is 1 to 60% by weight.